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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. END 727 DIVI/GSG 5468 07/02/2003 Randy R. Stephens 10/612,785 **EXAMINER** 27777 06/22/2004 7590 PHILIP S. JOHNSON MARMOR II, CHARLES ALAN JOHNSON & JOHNSON ART UNIT PAPER NUMBER ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 3736

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicatio	n No.	Applicant(s)	
Office Action Summary		10/612,78	5	STEPHENS ET AL.	
		Examiner		Art Unit	
		Charles A.		3736	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)	Responsive to communication(s) filed on				
2a)□	This action is FINAL . 2b)⊠ This action is non-final.				
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
· _					
5) <u>□</u> 6)⊠	 Claim(s) <u>14-24</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) <u>14-24</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or election requirement. 				
Application Papers					
9)⊠ The specification is objected to by the Examiner. 10)□ The drawing(s) filed on is/are: a)□ accepted or b)□ objected to by the Examiner.					
10)[_]	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)					
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date					
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07022003</u>. 				Patent Application (PTO-152)	

1. The Preliminary Amendment filed July 2, 2003 is acknowledged. Claims 1-13 have been canceled. New claims 14-24 have been added. Claims 14-24 are pending.

Specification

- 2. The disclosure is objected to because of the following informalities: In the first paragraph of the specification, added in the Preliminary Amendment filed July 2, 2003, the current status of the parent application should be provided. Appropriate correction is required.
- 3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 14-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al. ('469). Burbank et al. teach a method and apparatus for automated biopsy and collection of soft tissue. The apparatus includes a rotatable elongated piercing element 44 and an elongated cutter

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68 disposed within the piercing element. The piercing element has a sharpened distal end 45 and a port 46 proximal thereto for receiving a tissue mass. The cutter is adapted to translate and rotate within the elongated piercing element to harvest a tissue mass received within the port of the piercing element. The elognated piercing element is operatively associated with the cutter. Rotation of the piercing element is operatively associated with rotation of the cutter through the control unit 118. Rotation of the cutter and rotation of the piercing element may also be "associated" by rotating the housing 14 of the apparatus a predetermined number of degrees. The control unit 118 controls rotation of the piercing element and a device 48,52 for automatically rotating the piercing element. Multiple samples can be obtained about a longitudinal axis of the piercing element without manually rotating the piercing element. A portion 48 of the device for automatically rotating the piercing element is at least partially disposed on the cutter when apparatus is assembled and the cutter extends through the proximal portion of the piercing element. In operation, the biopsy probe is selectively rotated about a longitudinal axis thereof by rotating the piercing element a predetermined number of degrees in association with motion of the cutter in that the piercing element is rotated after the cutter is rotated and translated to sever a tissue sample received within the port.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 14-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-9 and 13 of U.S. Patent No. 6,620,111. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent. The limitations of claims 14, 16, 18 and 19 of the instant application are recited in claims 1 and 7 of the patent. The limitations of claims 15 and 20 of the instant application are recited in claims 3 and 9 of the patent. The limitations of claims 17 of the instant application are recited in claims 2 and 8 of the patent. The limitations of claims 21-24 of the instant application are recited in claims 13 of the patent. Since the broader claims of the instant application are anticipated by the claims of the patent, the claims are not patentably distinct.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Terwilliger ('970) teaches a biopsy needle set including an outer cannula and an inner cannula, where the cannulas are rotatable relative to one another. Evans ('229) teaches a rotating needle biopsy device. Burbank et al. ('727) teach a tissue acquisition system and method of use thereof.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is

(703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II Primary Examiner

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June 14, 2004